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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,992	05/03/2001	Wlfrid Lubisch	49500	7169
32116 7590 12/12/2008 WOOD, PHILLIPS, KATZ, CLARK & MORTIMER 500 W. MADISON STREET SUITE 3800 CHICAGO, IL 60661				
EXAMINER				
STOCKTON, LAURA LYNNE				
ART UNIT		PAPER NUMBER		
1626				
MAIL DATE		DELIVERY MODE		
12/12/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/830,992

Applicant(s)

LUBISCH ET AL.

Examiner

Laura L. Stockton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 14, 16-22, 24 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 14, 16-22, 24 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-10, 14, 16-22, 24 and 26 are pending in the application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on August 5, 2008 has been entered.

Election/Restrictions

During a telephone conversation with Herbert B. Keil on June 29, 2001, a provisional election was made

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with traverse to prosecute the invention of Group I {products and methods of claims 1-26}.

Rejections and objections made in the previous Office Action which do not appear below have been overcome. Therefore, arguments pertaining to these rejections and objections will not be addressed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-6, 8-10, 14, 16-22, 24 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No support in the specification or the original filed claims can be found for a number of changes that Applicant is/has added to the claims. See, for example, the following list.

In claim 1, there is no support for the entire definition of variable K (reproduced below). See originally filed claim 1 or the originally filed specification on page 7, lines 5-11 (reproduced below).

- 5 K is phenyl which may carry at most two radicals R, is $NR^{k1}R^{k2}$ (where R^{k1} and R^{k2} are as defined for R^{k1} and R^{k2} respectively), $NH-C_1-C_4$ -alkylphenyl, pyrrolidine, piperidine, 1,2,5,6-tetrahydropyridine, morpholine, trihydroazepine, piperazine, which may also be substituted by an alkyl radical
- 10 C_1-C_6 -alkyl, and homopiperazine, which may also be substituted by an alkyl radical C_1-C_6 -alkyl, and

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Applicant did not show where {page number(s) and line number(s)} persuasive support could be found in the originally filed specification or the originally filed claims. Applicants should specifically point out the support for any amendments. See M.P.E.P. §§ 714.02 and 2163.06. Therefore, the claims lack written description as such.

Response to Arguments

Applicant's arguments filed September 18, 2008 have been fully considered. Applicant argues that the definition of variable K is supported in the instant specification on page 7, lines 5-11. As stated in the previous Office Action, page 7, lines 5-11 do not support the definition of the K variable in the claims. For instance, the specification indicates that the phenyl defined by K is substituted with at the most two radicals R. However, the instant claims do not have such indication. In the specification, it is unclear

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if the language "is $NR^{k_1}R^{k_2}$ " is another definition of variable K or is the definition of variable R. For these reasons, the language found in the claims is unsupported.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 14, 16-22, 24 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1-3 and 7, the phrase "A compound of the formula I or II" should be changed to "A compound of formula I or II".

In claim 1, under the definition of R^{21} and R^{22} , " C_1 - C_4 alky 1" should be changed to " C_1 - C_4 alkyl".

In claim 1, the variable "X" should be lower case as shown in formulas I and II.

In claim 1, in the proviso under the definition of R^3 , the phrase "if $v = 0$ " should be changed to "if $v = 0$ " since v is defined as 0 or 1 and not O.

In claim 1, the variable "T" should be lower case as shown under the definition of R^{51} .

In claim 2, under the definition of R^{23} , an "or" is needed before the last substituent listed for proper Markush language format.

In claim 3, under the definition of R^{52} , an "or" should be added before " $COCF_3$ " for proper Markush language format as well as before the last possible substitutable substituent.

In claim 3, under the definition of R^3 , an "or" should be added for proper Markush language format.

Claim 7 does not conform to M.P.E.P. 608.01(m) since each claim must end with a period and no other periods may be used elsewhere in the claims except for abbreviations {i.e., "A compound of the formula I or II." }.

In claim 7, under the definition of R^1 , the phrase "one C atom of thealkyl radical" should be changed to "one C atom of the alkyl radical".

In claim 9, under the definition of R^5 , an "or" should be added before the last substituent listed for proper Markush language format.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

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from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4-6 and 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 10 of copending Application No. 11/536,994. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed invention is generically claimed in the

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compending application. See, for example, the first compound listed in independent claim 10 of the compending application.

The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating sepsis).

One skilled in the art would thus be motivated to prepare products embraced by the compending application to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, sepsis. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed September 18, 2008 have been fully considered. Applicant stated that a Terminal Disclaimer will be filed once all other issues have been resolved.

Claims 1-6, 8-10, 14, 16-22, 24 and 26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 and 7-22 of U.S. Patent No. 6,696,437. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed invention is generically claimed in the patent.

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., diabetes mellitus).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, diabetes mellitus. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Response to Arguments

Applicant's arguments filed September 18, 2008 have been fully considered. Applicant stated that a

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Terminal Disclaimer will be filed once all other issues have been resolved.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/Laura L. Stockton/
Laura L. Stockton
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

December 13, 2008